# 10/535666 JC06 Rec'd PCT/PTO 19 MAY 2005

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3 March 2005

The Commissioner of Patents Woden, A.C.T. 2606

Dear Commissioner,

Re:

International Patent Application No. PCT/AU2003/001552

Title:

Centrifugal Device and Method Using Same

Applicant:

Bio-Molecular Holdings Pty Limited

Our Ref: 021081PC/KF

We refer to the written opinion mailed 4 August 2004.

In connection with matters raised in the opinion, the applicants request that page 2 of the description and claim page 10 be replaced with page 2 and 10 to 12 submitted herewith.

Page 2 has been amended merely to bring the description into conformity with the independent claims as amended.

With regard to the claims:

claim 1 has been amended:

former claim 2 has been renumbered as claim 16 and amended; and new claims 2 to 15 and 17 to 26 have been added.

With regard to amended claims 1 and 2, changes have been made in accordance with observations given in box VIII of the opinion. Specifically:

the binding partners have been defined as "molecular entities"; the rotor recited in claim 1 has been qualified as a "centrifuge" rotor; it is now recited in claim 1 that reaction wells are attached to the rotor; and it is now recited in claim 1 that the light detection system is "stationary". EST AVAILABLE COPY

The new claims are directed to matter present in the application as filed. The source of subject matter of claims is given in the following table.

Claims	Location of disclosure
2	Page 3, lines 17 and 18
3	Page 4, lines 2 and 3
4	Page 4, line 7
5	Page 4, lines 11 and 12
6	Page 4, lines 14 and 15
7	Page 4, lines 16 and 17
8	Page 4, lines 17 to 20
9	Page 4, lines 21 and 22
10	Page 4, lines 26 to 28
11	Page 4, lines 28 to 30
12	Page 4, lines 30 and 31
13	Page 5, lines 1 to 5
14	Page 5, lines 6 to 13
15	Page 5, lines 17 to 25
17	Page 3, table at line 12
18	Page 5, lines 29 to page 6, line 1
19	Page 6, lines 13 and 14
20	Page 6, lines 14 to 16
21	Page 6, lines 23 and 24
22	Page 6, line 24
23	Page 6, lines 30 and 31
24	Page 6, line 32
25	Page 7, lines 2 and 3
26	Page 7, lines 4 and 5
27	Page 7, lines 7 and 8

To aid the examiner's understanding of the changes to claims 1 and 2 of the application as filed, a "marked-up" copy of page 10 is enclosed on which added text is underlined and deleted text struck-through.

We now turn to the statements made in box V of the opinion concerning the novelty of original claims 1 and 2. Each citation will be dealt with in turn.

## WO 01/61702

The documents specifically describes a method of detecting chitinous contaminants in non-chitinous material. While a binding assay with optical detection of a bound component may be described, there is no disclosure of binding a first molecular entity to

second molecular entity, the latter being located at an attachment zone. More specifically in the context of the citation, there is no disclosure—or even a suggestion—of attaching chitinous material at a particular zone of a centrifuge, allowing a mixture containing a fluorescently-labelled (for example) lectin to contact the chintinous material, and centrifuging mixture away from the attachment zone. Rather according to the citation, the centrifugation is used to deposit the mixture against a wall of the centrifuge tube on which deposited material a fluorometric reading is taken.

Since there is no specific disclosure or even a hint of the device and method the subject of the claims of the present application, the citation is not on anticipation.

### WO 95/31731

As indicated by the title of the citation disclosed is a method and apparatus for detecting blood group antigens and antibodies. The method comprises allowing erythrocytes to interact with a plurality of particles that have an immunoglobulin-binding ligand coupled thereto. The particles—while being contained within a centrifuge tube—do not, however, constitute an attachment zone on the surface of the centrifuge tube as called for in the claims of the present application. The citation is not, therefore, an anticipation of what is claimed.

### US 3,763,374

This patent merely discloses a rotor having a plurality of sample analysis cuvettes from which fluorometric and photometric measurements can be made but from different portions of the cuvette. These features alone differentiate the citation from the present invention as claimed in that fluorometric or photometric measurements are taken at the same portion of the reaction well in the latter case. Moreover, there is no disclosure or suggestion of an attachment zone in the cuvettes of the citation where the binding partner interaction can be measured. The US patent citation, like the other citations, is thus not an anticipation of the claims.

The citations either alone or in any combination do not render the claims obvious, for as indicated above, the citations in no way suggest the inclusion of an attachment zone on the internal surface of a centrifuge tube or the like. A skilled person would furthermore have no motivation to move beyond the methods and devices disclosed in the citations since the disclosed methods achieve the desired ends.

In view of the non-relevance of the citations, the applicants believe that it is not necessary to insert into the description references to the citations as suggested by the examiner in box VIII of the opinion.

On behalf of the applicants, we respectfully request that the examiner issue a report in which it is indicated that all claims are novel and inventive.

Yours respectfully CULLEN & CO.

KEN FINNEY

Replacement specification pages 2 and 10 to 12 Marked-up copy of former page 10 Enc.

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#### **CLAIMS**

- 1. A device for measuring the binding of a first partner in an interaction to a second partner in said interaction, wherein said interaction partners are molecular entities, said device comprising:
- 5 an opaque temperature-controlled chamber having a centrifuge rotor therein, said rotor a) having at or near the periphery thereofof the rotor and attached thereto at least one radially positioned transparent reaction well, said reaction well having on an upper surface thereof an aperture for the addition of reagents theretoto the reaction well, said reaction well further including on an internal surface thereof at the end closest the axis of said rotor at least one attachment zone for said second interaction partner;
  - a stationary system for detecting light emitted or absorbed by said first interaction b) partner or an indicator molecule bound thereto; and
  - c) means for controlling the temperature of said chamber and the operation of said rotor.
- A method of measuring the binding of a first partner in an interaction to a second partner 2. in said interaction, wherein said interaction partners are molecular entities, said method 15 comprising the steps of:
  - a) delivering a quantity of second interaction partner to a reaction well of a device according to the first embodimentclaim 1 for attachment of said second interaction partner to an attachment zone of said reaction well;
- 20 b) combining a quantity of first interaction partner with said second interaction partner in said reaction well and incubating said mixture at a temperature and for a time to allow binding of said first interaction partner to said second interaction partner;
  - rotating said device rotor at a speed which displaces the mixture formed in step (b) away c) from said attachment zone; and
  - 25 d) measuring the amount of said first interaction partner bound to said second interaction partner via the fluorescence or absorbance of said first interaction partner or an indicator molecule bound thereto.

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